K062454

NOV - 3 2006

Section 1: 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Device Act 1990 and 21 CFR § 807.92.

I. General Information

Establishment	Siemens Medical Solutions. Inc. 51 Valley Stream Parkway Malvern. PA 19355
Registration Number	2240869
Manufacturer	Siemens AG. Bereich Med Henkestrasse 127 D-91052 Erlangen. Germany
Registration Number	8010024
Contact Person	Ms. Judy Campbell Technical Specialist, Regulatory Submissions 51 Valley Stream Parkway Malvern. PA 19355 Phone: (610)448-4918 Fax: (610) 448-1787
Device Name	Trade Name: MAGNETOM Systems -- I-class and T-class releases
Classification Name: CFR Section: Classification:	Magnetic Resonance Diagnostic Device 21 CFR § 892.1000 Class II

Performance Standards
None established under Section 514 the Food, Drug, and Cosmetic Act.

II. Safety and Effectiveness Information Supporting Substantial Equivalence.

Intended Use
The MAGNETOM Systems – I-class and T-class releases are indicated for use as magnetic resonance diagnostic devices (MRDD) that produce transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra, and that display the internal structure and/or function of the head, body, or extremities. These images and/or spectra, when interpreted by a trained physician, yield information that may assist in diagnosis.

They may also be used for imaging during interventional procedures performed with MR compatible devices such as, in room display and safe biopsy needles.

The MAGNETOM systems – I-class and T-class releases are based on the *syngo* MR B15 software upgrade will be available for the following MAGNETOM Family systems:

System	FDA Clearance Number	FDA Clearance Date
MAGNETOM Avanto	K032428	October 16, 2003
MAGNETOM Espree	K041112	July 21, 2004
MAGNETOM Symphony a Tim System	K050199	February 18, 2005
MAGNETOM Trio a Tim System	K050200	February 28, 2005

Siemens Medical Solutions, Inc., intends to offer a software and hardware upgrade *syngo* MR B15. The indications for use will stay exactly the same, with respect to the previous software versions mentioned in the comparison matrix.

Substantial Equivalence
The systems 1.5 T MAGNETOM Avanto, Espree, Symphony a Tim System and the 3 T MAGNETOM Trio a Tim System, I-class and T-class releases with *syngo* MR B15 are substantially equivalent to the following cleared medical devices:

System	FDA Clearance Number	FDA Clearance Date
MAGNETOM Avanto	K032428	October 16, 2003
MAGNETOM Espree	K041112	July 21, 2004
MAGNETOM Symphony a Tim System	K050199	February 18, 2005
MAGNETOM Trio a Tim System	K050200	February 28, 2005

with software platform *syngo* MR 2006A that was described in premarket notification K052164 that received FDA clearance on October 4, 2005.

General Safety and Effectiveness Concerns:

The introduction of the MAGNETOM systems - I-class and T-class releases with *syngo* MR B15 has no significant effect on the MR safety and performance parameters.

Siemens Medical Solutions is adding an upgrade in software and hardware to the currently available MAGNETOM Systems. The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of the device.

Risk management is ensured via Risk Analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing. To minimize electrical and mechanical hazards, Siemens adheres to recognized and established industry practices and standards.

The MAGNETOM Systems will conform to the FDA recognized NEMA Standards for the measurement of performance and safety parameters and the international IEC standard for safety issues with Magnetic Resonance Imaging Devices. This will assure that the performance of this device can be considered safe and effective with respect to the currently available MAGNETOM systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

NOV - 3 2006

Ms. Judith Campbell
Technical Specialist, Regulatory Submissions
Siemens Medical Solutions, Inc.
51 Valley Stream Parkway
MALVERN PA 19355

Re: K062454
Trade/Device Name: MAGNETOM Systems – I-class and T-class releases
Regulation Number: 21 CFR §892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: August 17, 2006
Received: August 22, 2006

Dear Ms. Campbell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K062454

Section 3: Indications for Use Statement

510(K) Number (if known): K062454

Device Name: **MAGNETOM Systems – I-Class and T-Class Releases**

Indications for Use:

The MAGNETOM Systems – I-class and T-class releases are indicated for use as magnetic resonance diagnostic devices (MRDD) that produce transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra, and that display the internal structure and/or function of the head, body, or extremities. These images and/or spectra, when interpreted by a trained physician, yield information that may assist in diagnosis.

They may also be used for imaging during interventional procedures performed with MR compatible devices such as, in room display and safe biopsy needles.

(Please do not write below this line- continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ OR Over-The-Counter Use ____

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062454